

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims

1. – 135. (Cancelled)

136. (Currently amended) A method of treating a subject in need comprising administering to the subject an effective amount of a composition, wherein:

- (a) the composition comprises particles of fenofibrate having ~~an effective average particle size~~ **a D50 particle size** of less than about ~~1200~~ **500** nm and at least one surface stabilizer;
- (b) the fenofibrate particles present in the composition redisperse in a biorelevant media; and
- (c) administration of the composition to a human subject in a fasted state is bioequivalent to administration of the composition to a human subject in a fed state, wherein bioequivalency of the composition is established by:
 - (i) a 90% Confidence Interval for AUC which is between 0.80 and 1.25; and
 - (ii) a 90% Confidence Interval for C_{max}, which is between 0.80 and 1.25.

137. (Cancelled)

138. (Cancelled)

139. (Cancelled)

140. (Previously presented) The method of claim 136, wherein the composition is bioequivalent to a micronized 54 mg fenofibrate oral solid dosage form.

141. (Previously presented) The method of claim 136, wherein the composition is bioequivalent to a micronized 160 mg fenofibrate oral solid dosage form.

142. (Previously presented) The method of claim 141, wherein the composition is a single daily dose.

143. (Previously presented) The method of claim 136, wherein the composition is bioequivalent to a micronized 200 mg fenofibrate oral solid dosage form.

144. (Previously presented) The method of claim 143, wherein the composition is a single daily dose.

145. (Previously presented) The method of claim 136, wherein the difference in AUC of the fenofibrate composition, when administered to a human subject in the fed versus the fasted state, is selected from the group consisting of less than about 35%, less than about 30%, less than about 25%, less than about 20%, less than about 15%, less than about 10%, less than about 5%, and less than about 3%.

146. (Previously presented) The method of claim 136, wherein the composition, when administered to a human subject at a dose of about 160 mg, presents an AUC of about 139 $\mu\text{g/mL.h}$.

147. (Previously presented) The method of claim 136, wherein the composition exhibits a T_{max} after administration to fasting human subjects selected from the group consisting of less than about 6 hours, less than about 5 hours, less than about 4 hours, less than about 3 hours, less than about 2 hours, less than about 1 hour, and less than about 30 minutes.

148. (Previously presented) The method of claim 136, wherein in comparative pharmacokinetic testing with a micronized fenofibrate 160 mg tablet or micronized fenofibrate 200 mg capsule, which are standard commercial formulations of microcrystalline fenofibrate, the composition exhibits a T_{max} selected from the group consisting of less than about 90%, less than about 80%, less than about 70%, less than about 50%, less than about 30%, and less than about 25% of the T_{max} exhibited by micronized fenofibrate tablet or capsule.

149. (Previously presented) The method of claim 136, wherein the fenofibrate or a salt thereof is present in the composition in an amount selected from the group consisting of:

- (a) about 50 to about 500 g/kg fenofibrate or a salt thereof per kg of composition;
- (b) about 100 to about 300 g/kg fenofibrate or a salt thereof per kg of composition;
- (c) about 200 to about 225 g/kg fenofibrate or a salt thereof per kg of composition; and
- (d) about 119 to about 224 g/kg fenofibrate or a salt thereof per kg of composition.

150. (Previously presented) The method of claim 136, wherein the composition comprises a dosage of about 145 mg of particles of fenofibrate or a salt thereof, wherein:

- (a) the dosage is therapeutically effective; and
- (b) the composition is bioequivalent to a micronized fenofibrate 160 mg tablet or 200 mg capsule, wherein bioequivalency, when administered to a human, is established by a 90% Confidence Interval of between 0.80 and 1.25 for both C_{max} and AUC.

151. (Previously presented) The method of claim 136, wherein the composition comprises a dosage of about 48 mg of particles of fenofibrate or a salt thereof, wherein:

- (a) the dosage is therapeutically effective; and
- (b) the composition is bioequivalent to a micronized fenofibrate 54 mg tablet, wherein bioequivalency, when administered to a human, is established by a 90% Confidence Interval of between 0.80 and 1.25 for both C_{max} and AUC.

152. (Previously presented) The method of claim 136, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate, wherein following administration to fasting human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.

153. (Previously presented) The method of claim 152, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate to fasting human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at two hours.

154. (Previously presented) The method of claim 152, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate to fasting human subjects the blood levels of fenofibric acid are at least 7.0 mg/mL at three hours.

155. (Previously presented) The method of claim 152, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate to fasting human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.

156. (Previously presented) The method of claim 136, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate or a salt thereof, and wherein following administration of the composition to fasting human subjects the blood levels of fenofibric acid are at least:

- (a) 1.0 mg/mL at one hour;
- (b) 6.5 mg/mL at two hours;
- (c) 7.0 mg/mL at three hours; and
- (d) 1.5 mg/mL at twenty-four hours.

157. (Previously presented) The method of claim 136, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate or a salt thereof, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.

158. (Previously presented) The method of claim 157, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate to high fat fed human subjects the blood levels of fenofibric acid are at least 3.0 mg/mL at two hours.

159. (Previously presented) The method of claim 157, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 6.0 mg/mL at four hours.

160. (Previously presented) The method of claim 157, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate to high fat fed human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at five hours.

161. (Previously presented) The method of claim 157, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate to high fat fed human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.

162. (Previously presented) The method of claim 136, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate or a salt thereof, and wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least:

- (a) 4.5 mg/mL at one hour;
- (b) 3.0 mg/mL at two hours;
- (c) 6.0 mg/mL at four hours;
- (d) 6.5 mg/mL at five hours; and
- (e) 1.5 mg/mL at twenty-four hours.

163. (Previously presented) The method of claim 136, wherein the fenofibrate or a salt thereof is selected from the group consisting of a crystalline phase, an amorphous phase, a semi-crystalline phase, a semi-amorphous phase, and mixtures thereof.

164. (Currently amended) The method of claim 136, wherein the **effective-average D50** particle size of the particles of fenofibrate or a salt thereof are selected from the group consisting of less than about ~~1100 nm, less than about 1000 nm, less than about 900 nm, less than about 800 nm, less than about 700 nm, less than about 600 nm, less than about 500 nm, less than about~~ 400 nm, less than about 300 nm, less than about 250 nm, less than about 200 nm, less than about 150 nm, less than about 100 nm, less than about 75 nm, and less than about 50 nm.

165. (Previously presented) The method of claim 136, wherein the particles of fenofibrate or a salt thereof have a D₉₉ of less than about 500 nm.

166. (Previously presented) The method of claim 136, wherein the particles of fenofibrate or a salt thereof have a D₅₀ of less than about 350 nm.

167. (Previously presented) The method of claim 136, wherein the particles of fenofibrate or a salt thereof have a mean particle size of less than about 100 nm.

168. (Previously presented) The method of claim 136, wherein the composition is formulated for administration selected from the group consisting of oral, pulmonary, rectal,

ophthalmic, colonic, parenteral, intracisternal, intravaginal, intraperitoneal, local, buccal, nasal, and topical administration.

169. (Previously presented) The method of claim 136, wherein the composition is formulated into a dosage form selected from the group consisting of liquid dispersions, oral suspensions, gels, aerosols, ointments, creams, tablets, and capsules.

170. (Previously presented) The method of claim 169, wherein the composition is formulated into a dosage form selected from the group consisting of tablets and capsules.

171. (Previously presented) The method of claim 170, wherein the composition is formulated into a tablet dosage form.

172. (Previously presented) The method of claim 136, wherein the composition is formulated into a dosage form selected from the group consisting of controlled release formulations, fast melt formulations, lyophilized formulations, delayed release formulations, extended release formulations, pulsatile release formulations, and mixed immediate release and controlled release formulations.

173. (Previously presented) The method of claim 136, wherein the composition further comprises one or more pharmaceutically acceptable excipients, carriers, or a combination thereof.

174. (Previously presented) The method of claim 136, wherein within about 5 minutes at least about 20%, at least about 30%, or at least about 40% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

175. (Previously presented) The method of claim 136, wherein within about 10 minutes at least about 40%, at least about 50%, about 60%, about 70%, or about 80% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising

sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

176. (Previously presented) The method of claim 136, wherein within about 20 minutes at least about 70%, at least about 80%, about 90%, or about 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

177. (Previously presented) The method of claim 136, wherein:

- (a) within about 5 minutes at least about 30% of the composition is dissolved;
- (b) within about 10 minutes at least about 70% of the composition is dissolved; and
- (c) within about 20 minutes at least about 90% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

178. (Previously presented) The method of claim 136, wherein:

- (a) within about 5 minutes at least about 40% of the composition is dissolved;
- (b) within about 10 minutes at least about 80% of the composition is dissolved; and
- (c) within about 20 minutes at least about 100% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

179. (Currently amended) The method of claim 136, wherein upon administration, the composition redisperses such that the redispersed particles of fenofibrate or a salt thereof have ~~an effective average~~ a D50 particle size of less than about ~~1200~~ 500 nm.

180. (Currently amended) The method of claim 179, wherein the redispersed particles of fenofibrate or a salt thereof have ~~an effective average~~ a D50 particle size selected from the group consisting of less than about ~~1100 nm, less than about 1000 nm, less than about 900~~

~~nm, less than about 800 nm, less than about 700 nm, less than about 600 nm, less than about 500 nm, less than about~~ 400 nm, less than about 300 nm, less than about 250 nm, less than about 200 nm, less than about 150 nm, less than about 100 nm, less than about 75 nm, and less than about 50 nm.

181. (Currently amended) The method of claim 136, wherein the composition redisperses in a biorelevant media such that the redispersed particles of fenofibrate or a salt thereof have ~~an effective average a D50~~ particle size of less than about ~~1200~~ 500 nm.

182. (Currently amended) The method of claim 181, wherein the redispersed particles of fenofibrate or a salt thereof have ~~an effective average a D50~~ particle size selected from the group consisting of less than about ~~1100 nm, less than about 1000 nm, less than about 900 nm, less than about 800 nm, less than about 700 nm, less than about 600 nm, less than about 500 nm, less than about~~ 400 nm, less than about 300 nm, less than about 250 nm, less than about 200 nm, less than about 150 nm, less than about 100 nm, less than about 75 nm, and less than about 50 nm.

183. (Previously presented) The method of claim 136, wherein the composition additionally comprises one or more active agents selected from the group consisting of HMG CoA reductase inhibitors and antihypertensives.

184. (Previously presented) The method of claim 136, wherein the subject is a human.

185. (Previously presented) The method of claim 136, wherein the method is used to treat a condition selected from the group consisting of hypercholesterolemia, hypertriglyceridemia, coronary heart disease, cardiovascular disorders, and peripheral vascular disease .

186. (Previously presented) The method of claim 136, wherein the method is used as adjunctive therapy to diet for the reduction of LDL-C, total-C, triglycerides, or Apo B in adult patients with primary hypercholesterolemia or mixed dyslipidemia.

187. (Previously presented) The method of claim 136, wherein the method is used as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia.

188. (Previously presented) The method of claim 136, wherein the method is used to decrease the risk of pancreatitis.
189. (Previously presented) The method of claim 136, wherein the method is used to treat indications where lipid regulating agents are typically used.
190. (Previously presented) The method of claim 136, wherein the composition comprises at least one primary surface stabilizer and at least one secondary surface stabilizer.
191. (Previously presented) The method of claim 136, wherein the surface stabilizer is selected from the group consisting of a non-ionic surface stabilizer, an ionic surface stabilizer, an anionic surface stabilizer, a cationic surface stabilizer, and a zwitterionic surface stabilizer.
192. (Currently amended) The method of claim 136, wherein the at least one surface stabilizer is selected from the group consisting of cetyl pyridinium chloride, gelatin, casein, phosphatides, dextran, glycerol, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, dodecyl trimethyl ammonium bromide, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, hydroxypropyl celluloses, hypromellose, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hypromellose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, 4-(1,1,3,3-tetramethylbutyl)-phenol polymer with ethylene oxide and formaldehyde, poloxamers; poloxamines, a charged phospholipid, dioctylsulfosuccinate, dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, alkyl aryl polyether sulfonates, mixtures of sucrose stearate and sucrose distearate, p-isononylphenoxypoly-(glycidol), decanoyl-N-methylglucamide; n-decyl β -D-glucopyranoside; n-decyl β -D-maltopyranoside; n-dodecyl β -D-glucopyranoside; n-dodecyl β -D-maltoside; heptanoyl-N-methylglucamide; n-heptyl- β -D-glucopyranoside; n-heptyl β -D-thioglucoside; n-hexyl β -D-glucopyranoside; nonanoyl-N-methylglucamide; n-nonyl β -D-glucopyranoside; octanoyl-N-methylglucamide; n-octyl- β -D-

glucopyranoside; octyl β -D-thioglucopyranoside; lysozyme, PEG-phospholipid, PEG-cholesterol, PEG-cholesterol derivative, PEG-vitamin A, random copolymers of vinyl acetate and vinyl pyrrolidone, a cationic polymer, a cationic biopolymer, a cationic polysaccharide, a cationic cellulosic, a cationic alginate, a cationic nonpolymeric compound, cationic phospholipids, cationic lipids, polymethylmethacrylate trimethylammonium bromide, sulfonium compounds, polyvinylpyrrolidone-2-dimethylaminoethyl methacrylate dimethyl sulfate, hexadecyltrimethyl ammonium bromide, phosphonium compounds, quaternary ammonium compounds, benzyl-di(2-chloroethyl)ethylammonium bromide, coconut trimethyl ammonium chloride, coconut trimethyl ammonium bromide, coconut methyl dihydroxyethyl ammonium chloride, coconut methyl dihydroxyethyl ammonium bromide, decyl triethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride bromide, C₁₂₋₁₅dimethyl hydroxyethyl ammonium chloride, C₁₂₋₁₅dimethyl hydroxyethyl ammonium chloride bromide, coconut dimethyl hydroxyethyl ammonium chloride, coconut dimethyl hydroxyethyl ammonium bromide, myristyl trimethyl ammonium methyl sulphate, lauryl dimethyl benzyl ammonium chloride, lauryl dimethyl benzyl ammonium bromide, lauryl dimethyl (ethenoxy)₄ ammonium chloride, lauryl dimethyl (ethenoxy)₄ ammonium bromide, N-alkyl (C₁₂₋₁₈)dimethylbenzyl ammonium chloride, N-alkyl (C₁₄₋₁₈)dimethyl-benzyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium chloride monohydrate, dimethyl didecyl ammonium chloride, N-alkyl and (C₁₂₋₁₄) dimethyl 1-naphthylmethyl ammonium chloride, trimethylammonium halide, alkyl-trimethylammonium salts, dialkyl-dimethylammonium salts, lauryl trimethyl ammonium chloride, ethoxylated alkyamidoalkyldialkylammonium salt, an ethoxylated trialkyl ammonium salt, dialkylbenzene dialkylammonium chloride, N-didecyldimethyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium, chloride monohydrate, N-alkyl(C₁₂₋₁₄) dimethyl 1-naphthylmethyl ammonium chloride, dodecyldimethylbenzyl ammonium chloride, dialkyl benzenealkyl ammonium chloride, lauryl trimethyl ammonium chloride, alkylbenzyl methyl ammonium chloride, alkyl benzyl dimethyl ammonium bromide, C₁₂ trimethyl ammonium bromides, C₁₅ trimethyl ammonium bromides, C₁₇ trimethyl ammonium bromides, dodecylbenzyl triethyl ammonium chloride, poly-diallyldimethylammonium chloride (DADMAC), dimethyl ammonium chlorides, alkyl dimethylammonium halogenides, tricetyl

methyl ammonium chloride, decyltrimethylammonium bromide, dodecyltriethylammonium bromide, tetradecyltrimethylammonium bromide, methyl trioctylammonium chloride, ~~POLYQUAT 10™~~, tetrabutylammonium bromide, benzyl trimethylammonium bromide, choline esters, benzalkonium chloride, stearalkonium chloride compounds, cetyl pyridinium bromide, cetyl pyridinium chloride, halide salts of quaternized polyoxyethylalkylamines, ~~MIRAPOL™~~, ~~ALKAQUAT™~~, alkyl pyridinium salts; amines, amine salts, amine oxides, imide azolinium salts, protonated quaternary acrylamides, methylated quaternary polymers, and cationic guar.

193. (Previously presented) The method of claim 136, wherein the composition comprises hypromellose, dioctyl sodium sulfosuccinate, and sodium lauryl sulfate as surface stabilizers.

194. (New) A method of treating a subject in need comprising administering to the subject an effective amount of a composition, wherein:

- (a) the composition comprises particles of fenofibrate having a mean particle size of less than about 500 nm and at least one surface stabilizer;
- (b) the fenofibrate particles present in the composition redisperse in a biorelevant media; and
- (c) administration of the composition to a human subject in a fasted state is bioequivalent to administration of the composition to a human subject in a fed state, wherein bioequivalency of the composition is established by:
 - (i) a 90% Confidence Interval for AUC which is between 0.80 and 1.25; and
 - (ii) a 90% Confidence Interval for C_{max} , which is between 0.80 and 1.25.

195. (New) The method of claim 194, wherein the composition is bioequivalent to a micronized 54 mg fenofibrate oral solid dosage form.

196. (New) The method of claim 194, wherein the composition is bioequivalent to a micronized 160 mg fenofibrate oral solid dosage form.

197. (New) The method of claim 196, wherein the composition is a single daily dose.

198. (New) The method of claim 194, wherein the composition is bioequivalent to a micronized 200 mg fenofibrate oral solid dosage form.
199. (New) The method of claim 198, wherein the composition is a single daily dose.
200. (New) The method of claim 194, wherein the difference in AUC of the fenofibrate composition, when administered to a human subject in the fed versus the fasted state, is selected from the group consisting of less than about 35%, less than about 30%, less than about 25%, less than about 20%, less than about 15%, less than about 10%, less than about 5%, and less than about 3%.
201. (New) The method of claim 194, wherein the composition, when administered to a human subject at a dose of about 160 mg, presents an AUC of about 139 $\mu\text{g/mL.h}$.
202. (New) The method of claim 194, wherein the composition exhibits a T_{max} after administration to fasting human subjects selected from the group consisting of less than about 6 hours, less than about 5 hours, less than about 4 hours, less than about 3 hours, less than about 2 hours, less than about 1 hour, and less than about 30 minutes.
203. (New) The method of claim 194, wherein in comparative pharmacokinetic testing with a micronized fenofibrate 160 mg tablet or micronized fenofibrate 200 mg capsule, which are standard commercial formulations of microcrystalline fenofibrate, the composition exhibits a T_{max} selected from the group consisting of less than about 90%, less than about 80%, less than about 70%, less than about 50%, less than about 30%, and less than about 25% of the T_{max} exhibited by micronized fenofibrate tablet or capsule.
204. (New) The method of claim 194, wherein the fenofibrate or a salt thereof is present in the composition in an amount selected from the group consisting of:
- (a) about 50 to about 500 g/kg fenofibrate or a salt thereof per kg of composition;
 - (b) about 100 to about 300 g/kg fenofibrate or a salt thereof per kg of composition;
 - (c) about 200 to about 225 g/kg fenofibrate or a salt thereof per kg of composition; and
 - (d) about 119 to about 224 g/kg fenofibrate or a salt thereof per kg of composition.

205. (New) The method of claim 194, wherein the composition comprises a dosage of about 145 mg of particles of fenofibrate or a salt thereof, wherein:
- (a) the dosage is therapeutically effective; and
 - (b) the composition is bioequivalent to a micronized fenofibrate 160 mg tablet or 200 mg capsule, wherein bioequivalency, when administered to a human, is established by a 90% Confidence Interval of between 0.80 and 1.25 for both C_{\max} and AUC.
206. (New) The method of claim 194, wherein the composition comprises a dosage of about 48 mg of particles of fenofibrate or a salt thereof, wherein:
- (a) the dosage is therapeutically effective; and
 - (b) the composition is bioequivalent to a micronized fenofibrate 54 mg tablet, wherein bioequivalency, when administered to a human, is established by a 90% Confidence Interval of between 0.80 and 1.25 for both C_{\max} and AUC.
207. (New) The method of claim 194, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate, wherein following administration to fasting human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.
208. (New) The method of claim 207, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate to fasting human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at two hours.
209. (New) The method of claim 207, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate to fasting human subjects the blood levels of fenofibric acid are at least 7.0 mg/mL at three hours.
210. (New) The method of claim 207, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate to fasting human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.
211. (New) The method of claim 194, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate or a salt thereof, and wherein following

administration of the composition to fasting human subjects the blood levels of fenofibric acid are at least:

- (a) 1.0 mg/mL at one hour;
- (b) 6.5 mg/mL at two hours;
- (c) 7.0 mg/mL at three hours; and
- (d) 1.5 mg/mL at twenty-four hours.

212. (New) The method of claim 194, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate or a salt thereof, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.

213. (New) The method of claim 212, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate to high fat fed human subjects the blood levels of fenofibric acid are at least 3.0 mg/mL at two hours.

214. (New) The method of claim 212, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 6.0 mg/mL at four hours.

215. (New) The method of claim 212, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate to high fat fed human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at five hours.

216. (New) The method of claim 212, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate to high fat fed human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.

217. (New) The method of claim 194, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate or a salt thereof, and wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least:

- (a) 4.5 mg/mL at one hour;

- (b) 3.0 mg/mL at two hours;
- (c) 6.0 mg/mL at four hours;
- (d) 6.5 mg/mL at five hours; and
- (e) 1.5 mg/mL at twenty-four hours.

218. (New) The method of claim 194, wherein the fenofibrate or a salt thereof is selected from the group consisting of a crystalline phase, an amorphous phase, a semi-crystalline phase, a semi-amorphous phase, and mixtures thereof.

219. (New) The method of claim 194, wherein the mean particle size of the particles of fenofibrate or a salt thereof is selected from the group consisting of less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 200 nm, less than about 150 nm, less than about 100 nm, less than about 75 nm, and less than about 50 nm.

220. (New) The method of claim 194, wherein the particles of fenofibrate or a salt thereof have a D_{99} of less than about 500 nm.

221. (New) The method of claim 194, wherein the particles of fenofibrate or a salt thereof have a D_{50} of less than about 350 nm.

222. (New) The method of claim 194, wherein the particles of fenofibrate or a salt thereof have a mean particle size of less than about 100 nm.

223. (New) The method of claim 194, wherein the composition is formulated for administration selected from the group consisting of oral, pulmonary, rectal, ophthalmic, colonic, parenteral, intracisternal, intravaginal, intraperitoneal, local, buccal, nasal, and topical administration.

224. (New) The method of claim 194, wherein the composition is formulated into a dosage form selected from the group consisting of liquid dispersions, oral suspensions, gels, aerosols, ointments, creams, tablets, and capsules.

225. (New) The method of claim 224, wherein the composition is formulated into a dosage form selected from the group consisting of tablets and capsules.

226. (New) The method of claim 225, wherein the composition is formulated into a tablet dosage form.
227. (New) The method of claim 194, wherein the composition is formulated into a dosage form selected from the group consisting of controlled release formulations, fast melt formulations, lyophilized formulations, delayed release formulations, extended release formulations, pulsatile release formulations, and mixed immediate release and controlled release formulations.
228. (New) The method of claim 194, wherein the composition further comprises one or more pharmaceutically acceptable excipients, carriers, or a combination thereof.
229. (New) The method of claim 194, wherein within about 5 minutes at least about 20%, at least about 30%, or at least about 40% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.
230. (New) The method of claim 194, wherein within about 10 minutes at least about 40%, at least about 50%, about 60%, about 70%, or about 80% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.
231. (New) The method of claim 194, wherein within about 20 minutes at least about 70%, at least about 80%, about 90%, or about 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.
232. (New) The method of claim 194, wherein:
- (a) within about 5 minutes at least about 30% of the composition is dissolved;
 - (b) within about 10 minutes at least about 70% of the composition is dissolved; and

(c) within about 20 minutes at least about 90% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

233. (New) The method of claim 194, wherein:

(a) within about 5 minutes at least about 40% of the composition is dissolved;
(b) within about 10 minutes at least about 80% of the composition is dissolved; and
(c) within about 20 minutes at least about 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

234. (New) The method of claim 194, wherein upon administration, the composition redisperses such that the redispersed particles of fenofibrate or a salt thereof have a mean particle size of less than about 500 nm.

235. (New) The method of claim 234, wherein the redispersed particles of fenofibrate or a salt thereof have a mean particle size selected from the group consisting of less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 200 nm, less than about 150 nm, less than about 100 nm, less than about 75 nm, and less than about 50 nm.

236. (New) The method of claim 194, wherein the composition redisperses in a biorelevant media such that the redispersed particles of fenofibrate or a salt thereof have a mean particle size of less than about 500 nm.

237. (New) The method of claim 236, wherein the redispersed particles of fenofibrate or a salt thereof have a mean particle size selected from the group consisting of less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 200 nm, less than about 150 nm, less than about 100 nm, less than about 75 nm, and less than about 50 nm.

238. (New) The method of claim 194, wherein the composition additionally comprises one or more active agents selected from the group consisting of HMG CoA reductase inhibitors and antihypertensives.
239. (New) The method of claim 194, wherein the subject is a human.
240. (New) The method of claim 194, wherein the method is used to treat a condition selected from the group consisting of hypercholesterolemia, hypertriglyceridemia, coronary heart disease, cardiovascular disorders, and peripheral vascular disease .
241. (New) The method of claim 194, wherein the method is used as adjunctive therapy to diet for the reduction of LDL-C, total-C, triglycerides, or Apo B in adult patients with primary hypercholesterolemia or mixed dyslipidemia.
242. (New) The method of claim 194, wherein the method is used as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia.
243. (New) The method of claim 194, wherein the method is used to decrease the risk of pancreatitis.
244. (New) The method of claim 194, wherein the method is used to treat indications where lipid regulating agents are typically used.
245. (New) The method of claim 194, wherein the composition comprises at least one primary surface stabilizer and at least one secondary surface stabilizer.
246. (New) The method of claim 194, wherein the surface stabilizer is selected from the group consisting of a non-ionic surface stabilizer, an ionic surface stabilizer, an anionic surface stabilizer, a cationic surface stabilizer, and a zwitterionic surface stabilizer.
247. (New) The method of claim 194, wherein the at least one surface stabilizer is selected from the group consisting of cetyl pyridinium chloride, gelatin, casein, phosphatides, dextran, glycerol, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan

esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, dodecyl trimethyl ammonium bromide, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, hydroxypropyl celluloses, hypromellose, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hypromellose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, 4-(1,1,3,3-tetramethylbutyl)-phenol polymer with ethylene oxide and formaldehyde, poloxamers; poloxamines, a charged phospholipid, dioctylsulfosuccinate, dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, alkyl aryl polyether sulfonates, mixtures of sucrose stearate and sucrose distearate, p-isononylphenoxypoly-(glycidol), decanoyl-N-methylglucamide; n-decyl β -D-glucopyranoside; n-decyl β -D-maltopyranoside; n-dodecyl β -D-glucopyranoside; n-dodecyl β -D-maltoside; heptanoyl-N-methylglucamide; n-heptyl- β -D-glucopyranoside; n-heptyl β -D-thioglucoside; n-hexyl β -D-glucopyranoside; nonanoyl-N-methylglucamide; n-noyl β -D-glucopyranoside; octanoyl-N-methylglucamide; n-octyl- β -D-glucopyranoside; octyl β -D-thioglucopyranoside; lysozyme, PEG-phospholipid, PEG-cholesterol, PEG-cholesterol derivative, PEG-vitamin A, random copolymers of vinyl acetate and vinyl pyrrolidone, a cationic polymer, a cationic biopolymer, a cationic polysaccharide, a cationic cellulosic, a cationic alginate, a cationic nonpolymeric compound, cationic phospholipids, cationic lipids, polymethylmethacrylate trimethylammonium bromide, sulfonium compounds, polyvinylpyrrolidone-2-dimethylaminoethyl methacrylate dimethyl sulfate, hexadecyltrimethyl ammonium bromide, phosphonium compounds, quarternary ammonium compounds, benzyl-di(2-chloroethyl)ethylammonium bromide, coconut trimethyl ammonium chloride, coconut trimethyl ammonium bromide, coconut methyl dihydroxyethyl ammonium chloride, coconut methyl dihydroxyethyl ammonium bromide, decyl triethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride bromide, C₁₂₋₁₅dimethyl hydroxyethyl ammonium chloride, C₁₂₋₁₅dimethyl hydroxyethyl ammonium chloride bromide, coconut dimethyl hydroxyethyl ammonium chloride, coconut dimethyl hydroxyethyl ammonium bromide, myristyl trimethyl ammonium methyl sulphate, lauryl dimethyl benzyl ammonium chloride, lauryl dimethyl

benzyl ammonium bromide, lauryl dimethyl (ethenoxy)₄ ammonium chloride, lauryl dimethyl (ethenoxy)₄ ammonium bromide, N-alkyl (C₁₂₋₁₈)dimethylbenzyl ammonium chloride, N-alkyl (C₁₄₋₁₈)dimethyl-benzyl ammonium chloride, N-tetradecylidmethylbenzyl ammonium chloride monohydrate, dimethyl didecyl ammonium chloride, N-alkyl and (C₁₂₋₁₄) dimethyl 1-naphthylmethyl ammonium chloride, trimethylammonium halide, alkyl-trimethylammonium salts, dialkyl-dimethylammonium salts, lauryl trimethyl ammonium chloride, ethoxylated alkyamidoalkyldialkylammonium salt, an ethoxylated trialkyl ammonium salt, dialkylbenzene dialkylammonium chloride, N-didecyl dimethyl ammonium chloride, N-tetradecyl dimethylbenzyl ammonium, chloride monohydrate, N-alkyl(C₁₂₋₁₄) dimethyl 1-naphthylmethyl ammonium chloride, dodecyl dimethylbenzyl ammonium chloride, dialkyl benzenealkyl ammonium chloride, lauryl trimethyl ammonium chloride, alkylbenzyl methyl ammonium chloride, alkyl benzyl dimethyl ammonium bromide, C₁₂ trimethyl ammonium bromides, C₁₅ trimethyl ammonium bromides, C₁₇ trimethyl ammonium bromides, dodecylbenzyl triethyl ammonium chloride, poly-diallyldimethylammonium chloride (DADMAC), dimethyl ammonium chlorides, alkyldimethylammonium halogenides, tricetyl methyl ammonium chloride, decyltrimethylammonium bromide, dodecyltriethylammonium bromide, tetradecyltrimethylammonium bromide, methyl trioctylammonium chloride, tetrabutylammonium bromide, benzyl trimethylammonium bromide, choline esters, benzalkonium chloride, stearalkonium chloride compounds, cetyl pyridinium bromide, cetyl pyridinium chloride, halide salts of quaternized polyoxyethylalkylamines, alkyl pyridinium salts; amines, amine salts, amine oxides, imide azolinium salts, protonated quaternary acrylamides, methylated quaternary polymers, and cationic guar.

248. (New) The method of claim 194, wherein the composition comprises hypromellose, dioctyl sodium sulfosuccinate, and sodium lauryl sulfate as surface stabilizers.

249. (New) A method of treating a subject in need comprising administering to the subject an effective amount of a composition, wherein:

- (a) the composition comprises particles of fenofibrate having a D90 particle size of less than about 700 nm and at least one surface stabilizer;

- (b) the fenofibrate particles present in the composition redisperse in a biorelevant media;
and
 - (c) administration of the composition to a human subject in a fasted state is bioequivalent to administration of the composition to a human subject in a fed state, wherein bioequivalency of the composition is established by:
 - (i) a 90% Confidence Interval for AUC which is between 0.80 and 1.25; and
 - (ii) a 90% Confidence Interval for C_{max} , which is between 0.80 and 1.25.
250. (New) The method of claim 249, wherein the composition is bioequivalent to a micronized 54 mg fenofibrate oral solid dosage form.
251. (New) The method of claim 249, wherein the composition is bioequivalent to a micronized 160 mg fenofibrate oral solid dosage form.
252. (New) The method of claim 249, wherein the composition is a single daily dose.
253. (New) The method of claim 249, wherein the composition is bioequivalent to a micronized 200 mg fenofibrate oral solid dosage form.
254. (New) The method of claim 249, wherein the composition is a single daily dose.
255. (New) The method of claim 249, wherein the difference in AUC of the fenofibrate composition, when administered to a human subject in the fed versus the fasted state, is selected from the group consisting of less than about 35%, less than about 30%, less than about 25%, less than about 20%, less than about 15%, less than about 10%, less than about 5%, and less than about 3%.
256. (New) The method of claim 249, wherein the composition, when administered to a human subject at a dose of about 160 mg, presents an AUC of about 139 $\mu\text{g/mL.h}$.
257. (New) The method of claim 249, wherein the composition exhibits a T_{max} after administration to fasting human subjects selected from the group consisting of less than about 6 hours, less than about 5 hours, less than about 4 hours, less than about 3 hours, less than about 2 hours, less than about 1 hour, and less than about 30 minutes.

258. (New) The method of claim 249, wherein in comparative pharmacokinetic testing with a micronized fenofibrate 160 mg tablet or micronized fenofibrate 200 mg capsule, which are standard commercial formulations of microcrystalline fenofibrate, the composition exhibits a T_{\max} selected from the group consisting of less than about 90%, less than about 80%, less than about 70%, less than about 50%, less than about 30%, and less than about 25% of the T_{\max} exhibited by micronized fenofibrate tablet or capsule.

259. (New) The method of claim 249, wherein the fenofibrate or a salt thereof is present in the composition in an amount selected from the group consisting of:

- (a) about 50 to about 500 g/kg fenofibrate or a salt thereof per kg of composition;
- (b) about 100 to about 300 g/kg fenofibrate or a salt thereof per kg of composition;
- (c) about 200 to about 225 g/kg fenofibrate or a salt thereof per kg of composition; and
- (d) about 119 to about 224 g/kg fenofibrate or a salt thereof per kg of composition.

260. (New) The method of claim 249, wherein the composition comprises a dosage of about 145 mg of particles of fenofibrate or a salt thereof, wherein:

- (a) the dosage is therapeutically effective; and
- (b) the composition is bioequivalent to a micronized fenofibrate 160 mg tablet or 200 mg capsule, wherein bioequivalency, when administered to a human, is established by a 90% Confidence Interval of between 0.80 and 1.25 for both C_{\max} and AUC.

261. (New) The method of claim 249, wherein the composition comprises a dosage of about 48 mg of particles of fenofibrate or a salt thereof, wherein:

- (a) the dosage is therapeutically effective; and
- (b) the composition is bioequivalent to a micronized fenofibrate 54 mg tablet, wherein bioequivalency, when administered to a human, is established by a 90% Confidence Interval of between 0.80 and 1.25 for both C_{\max} and AUC.

262. (New) The method of claim 249, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate, wherein following administration to fasting human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.

263. (New) The method of claim 262, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate to fasting human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at two hours.

264. (New) The method of claim 262, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate to fasting human subjects the blood levels of fenofibric acid are at least 7.0 mg/mL at three hours.

265. (New) The method of claim 262, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate to fasting human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.

266. (New) The method of claim 249, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate or a salt thereof, and wherein following administration of the composition to fasting human subjects the blood levels of fenofibric acid are at least:

- (a) 1.0 mg/mL at one hour;
- (b) 6.5 mg/mL at two hours;
- (c) 7.0 mg/mL at three hours; and
- (d) 1.5 mg/mL at twenty-four hours.

267. (New) The method of claim 249, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate or a salt thereof, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 4.5 mg/mL at one hour.

268. (New) The method of claim 267, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate to high fat fed human subjects the blood levels of fenofibric acid are at least 3.0 mg/mL at two hours.

269. (New) The method of claim 267, wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least 6.0 mg/mL at four hours.

270. (New) The method of claim 267, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate to high fat fed human subjects the blood levels of fenofibric acid are at least 6.5 mg/mL at five hours.

271. (New) The method of claim 267, wherein following administration of the composition comprising a dosage of about 160 mg of fenofibrate to high fat fed human subjects the blood levels of fenofibric acid are at least 1.5 mg/mL at twenty-four hours.

272. (New) The method of claim 249, wherein the composition comprises a dosage of about 160 mg of particles of fenofibrate or a salt thereof, and wherein following administration of the composition to high fat fed human subjects the blood levels of fenofibric acid are at least:

- (a) 4.5 mg/mL at one hour;
- (b) 3.0 mg/mL at two hours;
- (c) 6.0 mg/mL at four hours;
- (d) 6.5 mg/mL at five hours; and
- (e) 1.5 mg/mL at twenty-four hours.

273. (New) The method of claim 249, wherein the fenofibrate or a salt thereof is selected from the group consisting of a crystalline phase, an amorphous phase, a semi-crystalline phase, a semi-amorphous phase, and mixtures thereof.

274. (New) The method of claim 249, wherein the D90 particle size of the particles of fenofibrate or a salt thereof is selected from the group consisting of less than about 600 nm, less than about 500 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 200 nm, less than about 150 nm, less than about 100 nm, less than about 75 nm, and less than about 50 nm.

275. (New) The method of claim 249, wherein the particles of fenofibrate or a salt thereof have a D₉₉ of less than about 500 nm.

276. (New) The method of claim 249, wherein the particles of fenofibrate or a salt thereof have a D₅₀ of less than about 350 nm.

277. (New) The method of claim 249, wherein the particles of fenofibrate or a salt thereof have a mean particle size of less than about 100 nm.
278. (New) The method of claim 249, wherein the composition is formulated for administration selected from the group consisting of oral, pulmonary, rectal, ophthalmic, colonic, parenteral, intracisternal, intravaginal, intraperitoneal, local, buccal, nasal, and topical administration.
279. (New) The method of claim 249, wherein the composition is formulated into a dosage form selected from the group consisting of liquid dispersions, oral suspensions, gels, aerosols, ointments, creams, tablets, and capsules.
280. (New) The method of claim 279, wherein the composition is formulated into a dosage form selected from the group consisting of tablets and capsules.
281. (New) The method of claim 280, wherein the composition is formulated into a tablet dosage form.
282. (New) The method of claim 249, wherein the composition is formulated into a dosage form selected from the group consisting of controlled release formulations, fast melt formulations, lyophilized formulations, delayed release formulations, extended release formulations, pulsatile release formulations, and mixed immediate release and controlled release formulations.
283. (New) The method of claim 249, wherein the composition further comprises one or more pharmaceutically acceptable excipients, carriers, or a combination thereof.
284. (New) The method of claim 249, wherein within about 5 minutes at least about 20%, at least about 30%, or at least about 40% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

285. (New) The method of claim 249, wherein within about 10 minutes at least about 40%, at least about 50%, about 60%, about 70%, or about 80% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

286. (New) The method of claim 249, wherein within about 20 minutes at least about 70%, at least about 80%, about 90%, or about 100% of the composition is dissolved, wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

287. (New) The method of claim 249, wherein:

- (a) within about 5 minutes at least about 30% of the composition is dissolved;
- (b) within about 10 minutes at least about 70% of the composition is dissolved; and
- (c) within about 20 minutes at least about 90% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

288. (New) The method of claim 249, wherein:

- (a) within about 5 minutes at least about 40% of the composition is dissolved;
- (b) within about 10 minutes at least about 80% of the composition is dissolved; and
- (c) within about 20 minutes at least about 100% of the composition is dissolved,

wherein dissolution is measured in a discriminating aqueous media comprising sodium lauryl sulfate at 0.025 M, and wherein the rotating blade method (European Pharmacopoeia) is used to measure dissolution.

289. (New) The method of claim 249, wherein upon administration, the composition redisperses such that the redispersed particles of fenofibrate or a salt thereof have a D90 particle size of less than about 700 nm.

290. (New) The method of claim 289, wherein the redispersed particles of fenofibrate or a salt thereof have a D90 particle size selected from the group consisting of less than about 600 nm, less than about 500 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 200 nm, less than about 150 nm, less than about 100 nm, less than about 75 nm, and less than about 50 nm.

291. (New) The method of claim 249, wherein the composition redisperses in a biorelevant media such that the redispersed particles of fenofibrate or a salt thereof have a D90 particle size of less than about 700 nm.

292. (New) The method of claim 291, wherein the redispersed particles of fenofibrate or a salt thereof have a D90 particle size selected from the group consisting of less than about 600 nm, less than about 500 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 200 nm, less than about 150 nm, less than about 100 nm, less than about 75 nm, and less than about 50 nm.

293. (New) The method of claim 249, wherein the composition additionally comprises one or more active agents selected from the group consisting of HMG CoA reductase inhibitors and antihypertensives.

294. (New) The method of claim 249, wherein the subject is a human.

295. (New) The method of claim 249, wherein the method is used to treat a condition selected from the group consisting of hypercholesterolemia, hypertriglyceridemia, coronary heart disease, cardiovascular disorders, and peripheral vascular disease .

296. (New) The method of claim 249, wherein the method is used as adjunctive therapy to diet for the reduction of LDL-C, total-C, triglycerides, or Apo B in adult patients with primary hypercholesterolemia or mixed dyslipidemia.

297. (New) The method of claim 249, wherein the method is used as adjunctive therapy to diet for treatment of adult patients with hypertriglyceridemia.

298. (New) The method of claim 249, wherein the method is used to decrease the risk of pancreatitis.
299. (New) The method of claim 249, wherein the method is used to treat indications where lipid regulating agents are typically used.
300. (New) The method of claim 249, wherein the composition comprises at least one primary surface stabilizer and at least one secondary surface stabilizer.
301. (New) The method of claim 249, wherein the surface stabilizer is selected from the group consisting of a non-ionic surface stabilizer, an ionic surface stabilizer, an anionic surface stabilizer, a cationic surface stabilizer, and a zwitterionic surface stabilizer.
302. (New) The method of claim 249, wherein the at least one surface stabilizer is selected from the group consisting of cetyl pyridinium chloride, gelatin, casein, phosphatides, dextran, glycerol, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, dodecyl trimethyl ammonium bromide, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, hydroxypropyl celluloses, hypromellose, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hypromellose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, 4-(1,1,3,3-tetramethylbutyl)-phenol polymer with ethylene oxide and formaldehyde, poloxamers; poloxamines, a charged phospholipid, dioctylsulfosuccinate, dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, alkyl aryl polyether sulfonates, mixtures of sucrose stearate and sucrose distearate, p-isononylphenoxypoly-(glycidol), decanoyl-N-methylglucamide; n-decyl β -D-glucopyranoside; n-decyl β -D-maltopyranoside; n-dodecyl β -D-glucopyranoside; n-dodecyl β -D-maltoside; heptanoyl-N-methylglucamide; n-heptyl- β -D-glucopyranoside; n-heptyl β -D-thiogluconoside; n-hexyl β -D-glucopyranoside; nonanoyl-N-methylglucamide; n-nonyl β -D-glucopyranoside; octanoyl-N-methylglucamide; n-octyl- β -D-glucopyranoside; octyl β -D-

thioglucopyranoside; lysozyme, PEG-phospholipid, PEG-cholesterol, PEG-cholesterol derivative, PEG-vitamin A, random copolymers of vinyl acetate and vinyl pyrrolidone, a cationic polymer, a cationic biopolymer, a cationic polysaccharide, a cationic cellulosic, a cationic alginate, a cationic nonpolymeric compound, cationic phospholipids, cationic lipids, polymethylmethacrylate trimethylammonium bromide, sulfonium compounds, polyvinylpyrrolidone-2-dimethylaminoethyl methacrylate dimethyl sulfate, hexadecyltrimethyl ammonium bromide, phosphonium compounds, quarternary ammonium compounds, benzyl-di(2-chloroethyl)ethylammonium bromide, coconut trimethyl ammonium chloride, coconut trimethyl ammonium bromide, coconut methyl dihydroxyethyl ammonium chloride, coconut methyl dihydroxyethyl ammonium bromide, decyl triethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride bromide, C₁₂₋₁₅dimethyl hydroxyethyl ammonium chloride, C₁₂₋₁₅dimethyl hydroxyethyl ammonium chloride bromide, coconut dimethyl hydroxyethyl ammonium chloride, coconut dimethyl hydroxyethyl ammonium bromide, myristyl trimethyl ammonium methyl sulphate, lauryl dimethyl benzyl ammonium chloride, lauryl dimethyl benzyl ammonium bromide, lauryl dimethyl (ethenoxy)₄ ammonium chloride, lauryl dimethyl (ethenoxy)₄ ammonium bromide, N-alkyl (C₁₂₋₁₈)dimethylbenzyl ammonium chloride, N-alkyl (C₁₄₋₁₈)dimethyl-benzyl ammonium chloride, N-tetradecylidmethylbenzyl ammonium chloride monohydrate, dimethyl didecyl ammonium chloride, N-alkyl and (C₁₂₋₁₄) dimethyl 1-naphthylmethyl ammonium chloride, trimethylammonium halide, alkyl-trimethylammonium salts, dialkyl-dimethylammonium salts, lauryl trimethyl ammonium chloride, ethoxylated alkyamidoalkyldialkylammonium salt, an ethoxylated trialkyl ammonium salt, dialkylbenzene dialkylammonium chloride, N-didecyldimethyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium, chloride monohydrate, N-alkyl(C₁₂₋₁₄) dimethyl 1-naphthylmethyl ammonium chloride, dodecyldimethylbenzyl ammonium chloride, dialkyl benzenealkyl ammonium chloride, lauryl trimethyl ammonium chloride, alkylbenzyl methyl ammonium chloride, alkyl benzyl dimethyl ammonium bromide, C₁₂ trimethyl ammonium bromides, C₁₅ trimethyl ammonium bromides, C₁₇ trimethyl ammonium bromides, dodecylbenzyl triethyl ammonium chloride, poly-diallyldimethylammonium chloride (DADMAC), dimethyl ammonium chlorides, alkyl dimethylammonium halogenides, tricetyl

methyl ammonium chloride, decyltrimethylammonium bromide, dodecyltriethylammonium bromide, tetradecyltrimethylammonium bromide, methyl trioctylammonium chloride, tetrabutylammonium bromide, benzyl trimethylammonium bromide, choline esters, benzalkonium chloride, stearylalkonium chloride compounds, cetyl pyridinium bromide, cetyl pyridinium chloride, halide salts of quaternized polyoxyethylalkylamines, alkyl pyridinium salts; amines, amine salts, amine oxides, imide azolinium salts, protonated quaternary acrylamides, methylated quaternary polymers, and cationic guar.

303. (New) The method of claim 249, wherein the composition comprises hypromellose, dioctyl sodium sulfosuccinate, and sodium lauryl sulfate as surface stabilizers.